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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,078	01/03/2002	Jorg Schreiber	BEIERSDORF 724-WCG	5707

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EXAMINER
YU, GINA C

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/890,078	SCHREILBER, JORG	
	Examiner	Art Unit	
	Gina C. Yu	1617	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of Amendment filed on November 15, 2002. Claims 3-20 are pending. Claim rejections under 35 U.S.C. § 112, second paragraph, are withdrawn in view of claim amendment. Claim rejections under 35 U.S.C. § 103 are withdrawn and new rejections are made in view of the claim amendment.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on June 7, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 10, the claim limitation excluding "viscosity enhancing modifiers" is not described in the original disclosure. The disclosure in p. 14, lines 10 – 12 of the specification which applicants assert provides support for this limitation, in fact merely indicates that prior art lecithin gels "do not represent microemulsion gels since . . . a corresponding viscosity-increasing substance for the continuous phase is missing." The

specification in fact discloses that conventional cosmetic auxiliaries including polymers are used in the present invention. See spec. p. 43, lines 6 – 14. Examiner views that the claim amendment now presents a subject matter which was not described in the original disclosure, and does not convey to a skilled artisan that applicants had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 10 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The term "polymeric viscosity enhancers" render claim 10 vague and indefinite. It is not clear what polymeric thickeners are to be excluded. The metes and bounds of the scope of the claim are unclear.

The remaining claims are rejected as depending on the indefinite base claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman (US 6113921) and in view of Ponsanski, or alternatively, over Friedman in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery Systems, 1990) and Ponsanski.

Friedman teaches method of making microemulsions. See Examples 1, 4, and 20. The process of preparing an oil phase comprising lecithin, and mixing with a water phase comprising Pluronic F-68 is taught.

While the reference does not teach that the resulting mixture increases in viscosity, examiner views that the prior art method steps, which meet the method steps of the instant claims, obviously results in higher viscosity.

Friedman fails to teach adding water to dilute the emulsion.

Ponsanski teaches that in preparing o/w microemulsion containing lecithin, the water is later added to dilute the concentrated emulsion.

Given the general teaching of making o/w microemulsions in Friedman, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition by further adding water as motivated by Ponsanski because of the expectation of successfully producing a diluted composition.

Alternatively, while the Friedman reference does not teach that the resulting mixture increases in viscosity, water can be added later to dilute the emulsion, examiner views that the instant claim is obvious over Friedman in view of Ansel and Ponsanski.

Ansel teaches that "as the internal concentration of an emulsion is increased, there is an increase in the viscosity of the emulsion to a certain point, after which the viscosity decreases sharply", at which point an inversion is formed. See p. 243, bridging paragraph. The reference further goes on to teach that emulsions are prepared without inversion with as much as about 75 % of the volume of the product being internal phase.

Ponsanski is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have expected that in the process of making the microemulsions in Friedman, the viscosity of the resulting composition would increase upon the mixture of the internal and external phases, as taught by Ansel. The skilled artisan who desires to formulate a diluted composition would have been motivated to further add water as suggested by Ponsanski.

2. Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman and Ponsanski and as applied to claim 15 above, and further in view of Von Corswant.

While Friedman teaches to treat the emulsion at the temperature of 45-55 °C, the reference teaches heating the phases at least at 60 °C.

Ponsanski, discussed above, teaches heating active ingredients in phospholipid/co-emulsifier phase up to 60 °C and stirring, and then diluting with water.

Von Corswant teaches that microemulsions can be prepared by mixing the components together in no particular order. See p. 3, Preparation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have to have modified the method of making microemulsion in Friedman by heating phospholipid/co-emulsifier up to 60°C to dissolve active ingredients as suggested by Ponsanski. It would have been further obvious to the skilled artisan that components can be mixed in no particular order, as suggested by Von Corswant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10 an 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6468551 B1. Although the conflicting claims are not identical, they are not

patentably distinct from each other because both sets of claims are directed to oil-in-water microemulsions comprising o/w emulsifiers, lecithin or the derivatives thereof, and an optionally w/o emulsifiers.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
February 10, 2003

SREENI PADMANABHAN
PRIMARY EXAMINER
2/10/03